

Maile Gradison

Partner

Washington, D.C.

Biography

When it comes to solving the challenges facing the food industry and their trade associations, Maile Gradison handles it all.

She has considerable experience with the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA), having worked with numerous companies and trade associations on all aspects of the law since the day it was signed. She translates her in-depth knowledge of FSMA into practical solutions for companies working on implementation strategies. She also frequently presents trainings related to FSMA compliance and preparedness. Reflecting her deep involvement with all things FSMA, Maile is a Food Safety Preventive Controls Alliance (FSPCA) Lead Instructor for the Preventive Controls for Human Food training and an FSPCA Trainer of Trainers and Lead Instructor for the Foreign Supplier Verification Programs (FSVP) training.

Maile is known for helping companies become and remain compliant with regulations overseen by federal agencies such as the FDA and U.S. Department of Agriculture (USDA). She helps companies navigate tough situations involving product recalls, government inspections, and other enforcement actions such as Warning Letters and import detentions.

Maile also provides clients with advice on public policy issues and strategies for affecting regulatory change. She has vast experience advocating to FDA, including preparing comments on agency rulemakings.



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Practices

Administrative and Public Law

Crisis Leadership Team

Food Law

Government Relations and Public Affairs

Marketing and Advertising

Industries

Consumer

Areas of focus

Food and Beverages

Food Recalls

Food Compliance and Enforcement

Additionally, Maile helps clients with food labeling requirements and development of label and advertising claims.

Maile is a frequent speaker and contributor to industry publications. Prior to joining us, she served as a judicial clerk to the Honorable Charles F. Lettow of the U.S. Court of Federal Claims. Maile graduated with high honors from The George Washington University Law School, where she served as executive editor of *The George Washington Law Review*.

Representative experience

Presented at the 3rd Annual Food Label Claims Conference, "Post-COVID Development of Functional and Immunity Claims."

Counseled companies and trade associations on the requirements under FSMA final rules.

Developed FSMA implementation strategies for major multinational food companies.

Prepared responses to Warning Letters and 483s.

Advised on product and claims development.

Advised on advertising substantiation requirements.

Prepared dozens of comments for companies and trade associations on FSMA rulemakings.

Helped food companies navigate recalls.

Delivered training sessions at clients' corporate quality and food safety meetings.

Awards and rankings

- Food & Beverages: Regulatory & Litigation (Nationwide), Associate to Watch, *Chambers USA*, 2015-2016
- Food & Beverages: Regulatory & Litigation (Nationwide), Up and coming, *Chambers USA*, 2018-2019
- Food & Beverages: Regulatory & Litigation (Nationwide), Rank 2, *Chambers USA*, 2022

Food Legislation and Regulatory Policy Development

Trade Association Governance

Food Advertising and Regulation

International Regulatory Compliance

Medical Foods and Dietary Supplements

Education and admissions

Education

J.D., The George Washington University Law School, with high honors; Order of the Coif, 2007

B.S., Tulane University, summa cum laude, 2004

Bar admissions and qualifications

District of Columbia

Virginia

Latest thinking and events

- News
 - FDA proposes redesign for Human Foods Program - US
- News
 - U.S. Food Law Preview - Key issues affecting the food industry in 2023
- News
 - OMB releases Fall 2022 Unified Agenda of Regulatory Actions
- News
 - FDA releases systematic review of the scientific literature on food safety culture
- News
 - Reagan-Udall Foundation issues report with recommendations for strengthening FDA's Human Foods Program
- News
 - FSMA Update: FDA issues final traceability rule for certain foods